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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,704

12/12/2005

Richard James Lewis

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EXAMINER

AUDET, MAURY A

ART UNIT

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1654

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,704	<b>Applicant(s)</b> LEWIS ET AL.	
	<b>Examiner</b> MAURY AUDET	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/29/08.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 11 and 15-21 is/are pending in the application.  
     4a) Of the above claim(s) 11 and 17-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-16 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6 and 7 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The present Application has been transferred from former Examiner Young to the present Examiner.

Applicant's amendment and response are acknowledged.

#### ***Restriction election and traversal acknowledged***

The FINAL restriction requirement is maintained as provided previously, as to the methods, BUT, the peptides have been rejoined. Specifically, Applicant's request for the rejoinder of the remaining, amended five (5) SEQ ID NOS: 5-6, 9, and 10-11, as well as the amended genus peptide formula of claim 1 is EXTENDED.

Claim 5, product, is hereby rejoined.

The method claims will be rejoined under In re Ochiai upon the Allowability of the product claims to which they depend.

Thereafter, upon allowability of any method claims formerly within a different group, the FINALITY of the restriction requirement as to these will be VACATED.

Claims 15-16 are directed to an allowable product. Based on Applicant's request of the Examiner to rejoin the product of claim 5, which the Examiner has extended, claim 5 has been rejoined and previously withdrawn from consideration as a result of a restriction requirement, and are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement, in part, 10/30/06, as set forth in the Office action**

**mailed on 10/30/06 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The original restriction requirement, as noted previously, was that Applicant's election with traverse of Group I, claims 1-7, and the species election of SEQ ID NO: 4, in the reply filed on December 4, 2006 is acknowledged. The traversal is on the ground(s) that the claims have unity of invention under PCT Rule 13.1. This is not found persuasive because it is proper to rely on evaluation of novelty or unobviousness when making a determination of unity of invention, the unity of invention of the instant application's claim set being broken by the prior art cited by the Examiner, Balaji et al. (*J. Biol. Chem.* 275(50):39516-22, 2000) does teach the special technical feature of the instant claims, the structure of the chi-conotoxins. In regards the linking claim 8 recited in Applicant's response on page 4, it is drawn to non-elected inventions II-VII. Claim 5 is withdrawn as being drawn to non-elected species, the elected species being found unpatentable (see below).

### ***Double Patenting Rejection***

The rejection is maintained for the reasons of record. The '088 application has the same priority date as the present application, and remains under examination on the merits as to one or more overlapping peptides (e.g. SEQ ID NO: 5). At such time as the present application be found to contain allowable subject matter, a Terminal Disclaimer will be required should the overlapping subject matter remain.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-3 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 5, 6, 12, 13, 15-21, 38-41, 43, 45, 47, and 49 of copending Application No. 10/537,088, is maintained for the reasons of record as indicated above.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the species of conotoxin peptide claimed in the instant 10/537,704 as the elected peptide species SEQ ID NO: 4 is part of the Markush group comprising the conotoxin peptides claimed in the copending 10/537,088 as SEQ ID NO: 4 (in copending claim 2) and SEQ ID NO: 5 (in copending claims 5 and 6). Claims depending from the copending claims 2, 5 and 6 are directed towards further narrowing the Markush group, rendering the instant SEQ ID NO: 4 of 10/537,704 as a species of an ever smaller genus. The peptide sequence SEQ ID NO: 3 (instant claims 1 and 2), which is the foundation of the instant claim set in 10/537,704 is similarly within the bounds of the SEQ ID NO: 4 of the copending 10/537,088.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Objections***

Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 6-7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In e.g. claim 3, now rejoined (amended genus of SEQ ID NO: 3) it is unclear what the variables of the invention are supposed to be, based on the use of the term “or”. Namely Xaa1 and Xaa2; OR ... one or more Cys...and/or Pro....and/or Tyr. As to "one or more Cys", does the OR in front thereof, indicate that Xaa1 and Xaa2 are not present? Or if present, that one or more Cys is not altered to D version.

If there is support, Applicant may wish to consider positively claim the invention, even if optional. Namely, replacing “or” with “optionally”, one or more Cys is the D-version, and optionally Pro and Tyr may be...4-hydroxy...4-methoxy..., respectively".

Alternatively, Applicant may consider any other amendment for which support is present, which does not expand the scope of the peptide search/examination, for which the Examiner has just agreed to rejoin, in order to clarify that which is the invention.

***Request for Information: In re Ochiai Rejoinder of Methods of Use Claims***

In anticipation of the future rejoinder of the myriad methods of use of these compounds, Applicant is asked to supply the Office with specification support (e.g. tests, etc.) or literature support that the native peptide of these modified peptides bearing a substantial core structure herein are known or have been shown to treat all these myriad of

***Conclusion***

Claims 15-16 are allowed.

**THIS ACTION IS MADE FINAL – as to the newly cited 35 USC 112 2<sup>nd</sup> Rejection, based on the Examiner’s willingness to rejoin and examine the restricted peptides, not originally elected.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Cecilia Tsang can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications



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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA, 4/13/09

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654